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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/027,792	12/20/2001	John R. Adler	1010497-991130	2683

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EXAMINER

SOLANKI, PARIKHA

ART UNIT	PAPER NUMBER
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3737

DATE MAILED: 12/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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**Office Action Summary**

Application No.

10/027,792

Applicant(s)

ADLER, JOHN R.

Examiner

Parikha Solanki

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 16 February 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 30-61 and 63-65 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 30-57, 58-61 and 63-65 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Response to Arguments*

1. Applicant's arguments filed on 15 February 2006 have been fully considered but they are not persuasive.

Applicant contends that Sirimanne (US Patent No. 6,356,782) and Schweikard (US Patent No. 6,144,875) fail to teach "a fiducial comprising a body portion and an anchor member coupled to the body portion, the body portion having a housing, and the anchor member drawn into the housing in an unanchored position." Applicant further contends that the marker of Sirimanne ('782) is not detected by electromagnetic radiation.

During patent examination, the pending claims are given their broadest reasonable interpretation commensurate with the scope of the invention provided in the specification. For further detail regarding the policies and procedures set forth regarding broadest reasonable interpretation, see MPEP § 2111.

Regarding marker detection, Examiner directs Applicant's attention to the Abstract of Sirimanne ('782), which explicitly provides a marking device and method to determine the location of the marker by "radiographic ... or other non-invasive imaging techniques." As provided by Merriam Webster (<http://www.m-w.com>), a radiograph is defined as "a picture produced on a sensitive surface by a form of radiation other than visible light; specifically: an X-ray or gamma ray photograph". Gamma rays inherently constitute electromagnetic radiation. Therefore, one of ordinary skill in the art at the time of invention would consider it obvious that Sirimanne ('782) clearly teaches marker detection by electromagnetic radiation.

Regarding marker structure, Examiner directs Applicant's attention to elements **150** and **154** of Figures 1A and 1B of Sirimanne ('782), which explicitly shows a "cylindrical body and two ring-shaped markers" (col. 5 lines 24-26). One of ordinary skill in the art would consider the cylindrical body of Sirimanne ('782) to be equivalent to the body housing claimed in the instant application. Sirimanne ('782) further provides that a suture or wire marker may be included within the body of any other type of marker, including aforementioned marker **150**. One of ordinary skill in the art would consider it reasonable and obvious to interpret the suture or wire marker of Sirimanne ('782) to be equivalent to the anchor member claimed in the instant application.

Since Applicant's arguments are found to be unpersuasive, the rejections set forth in the previous Office Action are maintained and reiterated below.

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***Claim Rejections - 35 USC § 103***

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. Claims 30-57, 59-61, and 63-65 are rejected under 35 U.S.C. 103(a) as being unpatentable over *Sirimanne et al* (US 6,356,782) in view of *Schweikard et al* (US 6,144,875). *Sirimanne et al* '782 substantially disclose all claimed features in claims 30-57, 59-61, and 63-65.

***Claims 30, 46, 48, 49, 52, 54, 55, 59-61, 64, and 65:*** *Sirimanne et al* '782 disclose a method and device for subcutaneously marking region of interest by depositing a fiducial marker into a target region with biopsy needle where the fiducial marker is radiopaque or echogenic so that the marker is visible via imaging device such as x-ray mammography or ultrasound (col. 2, line 54 - col. 3, line 6; col. 3, lines 33-47; col. 9, lines 29-31). However, *Sirimanne et al* '782 does not specify that needle biopsy surgery and treatment use stereotaxic feedback to monitor the process. This particular deficiency in *Sirimanne et al* '782 is well known in the art as evident by *Schweikard et al* '875 where a target organ 151 is imaged by a stereotaxic x-ray device as shown in figure 6 with internal markers 152 (col. 5, lines 31-46). The internal markers are no different than fiducial markers such as *Sirimanne et al*'s to analyze and localize the target image. Therefore it would have been obvious to one having an ordinary skill in the art at the time the invention was made to apply the teachings of *Schweikard et al*'s stereotaxic imaging system with *Sirimanne et al*'s fiducial marker deposition to achieve the claimed invention.

***Claim 31:*** *Schweikard et al* '875 further teach tracking the target region during the stereotaxic radiosurgery (see col. 3, line 39-col. 4, line 53" referring to tracking the target region while performing radiosurgery).

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**Claim 32:** Schweikard et al '875 further teach applying radiation treatment to the target region (see col. 4, lines 9-22).

**Claim 33:** Schweikard et al.'875 further teach anchoring the fiducial in the target region to prevent migration of the fiducial relative to the target region (see col. 5, lines 8-30, referring to the attachment of the fiducials or markers on the organ of interest so that organ can be traced for accurate treatment).

**Claims 34 and 35:** Schweikard et al '875 further teach viewing the fiducial using an x-ray imager, wherein the fiducial comprises a radiopaque, material or viewing the fiducial using an ultrasonic imager, wherein the fiducial comprises an ultrasonic opaque material (see col. 5, lines 20-30).

**Claims 36-45, 47, 50, 53, and 57:** Sirimanne et al '782 disclose the markers being anchored to the area of interest via wire or suture introduced from the same lumen where the markers are placed in the region of interest. And since the suture or wire is introduced after the markers are placed in the region of interest, it is interpreted as having unanchored position prior to affixing the markers to the surrounding tissue, i.e. anchored position (col. 6, lines 56-67). In addition, the shape and composition of the anchors as described in the applicant's claims 37-43 are design choice where the end result of the anchoring is functionally equivalent to Sirimanne et al's anchoring apparatus.

**Claims 51, 56, and 63:** Sirimanne et al '782 further disclose that the method is used to target tumor (col. 1, lines 34-42).

### **Conclusion**

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37


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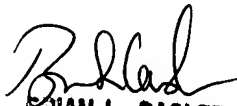
CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parikha Solanki whose telephone number is 571.272.3248. The examiner can normally be reached on M-F, 8 - 4:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on 571.272.4956. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Parikha Solanki  
Examiner – Art Unit 3737

  
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